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United States Department of Agriculture

FOOD AND DRUG ADMINISTRATION

SERVICE AND REGULATORY ANNOUNCEMENTS

Food and Drug No. 3
(First Revision)

CERTIFICATION OF COAL-TAR FOOD COLORS

CONTENTS

INTRODUCTION

The procedure for the certification of coal-tar food colors outlined in this announcement supersedes that previously followed by the Department of Agriculture as published in Service and Regulatory Announcement, Food and Drug No. 3.

The Food and Drug Administration is hereby authorized to certify coal-tar food colors which meet the accompanying requirements.

R. W. Dunlap,
Acting Secretary of Agriculture.

Washington, D. C., *July 15, 1931.*

PURPOSE OF CERTIFICATION AND USE OF CERTIFIED DYES

As ordinarily manufactured for textile or other industrial purposes, dyes often contain impurities, some of which are harmless, whereas others are toxic. These impurities may not detract from the value of the dyes for industrial use, but they would be highly objectionable in a substance designed for human consumption. Practically all dyes at one stage or another of their manufacture are treated with sulfuric or nitric acid, both of which are frequently contaminated with arsenic. The vessels in which the dyes are made may also contain arsenic. Unless special precautions are taken the dyes may therefore be seriously contaminated with arsenic compounds. If the manufacturing processes are carried on in vessels of lead or copper, appreciable quantities of these metals may be dissolved and contaminate the dye. Harmful intermediates and organic compounds are present in most industrial dyes. Uncombined intermediates and other organic compounds produced by side reactions during manufacture, even though comparatively harmless, are objectionable in food dyes, except in very small proportions. The standards of purity set for certified dyes necessitate special precautions in their manufacture and purification, in order that appreciable quantities of objectionable substances may not be present in the finished dyes. Certification by the Food and Drug Administration implies not only that the dye itself is harmless, but that it is uncontaminated by poisonous substances.

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The procedure of certification has been devised for the purpose of affording manufacturers of food colors and manufacturers of food products, as well as other consumers of food colors, a means of determining the suitability of these products for food use in so far as their purity and harmlessness are concerned. The use of color of any kind to conceal damage or inferiority in a food product is defined by the Federal food and drugs act as an adulteration and, when damage or inferiority is concealed, the employment of artificial color is not permissible, even though certified colors are used and their presence is declared on the label. In general, where colors are legitimately used in foods and beverages a statement on the label of the presence of artificial color is required.

As unpermitted coal-tar dyes or permitted dyes which have not been certified are likely to be harmful in themselves or to contain harmful impurities, manufacturers who sell them for food purposes or who use them in coloring food products may render themselves liable to prosecution and the dyes or the foods colored with them liable to seizure under the Federal food and drugs act. The same objections apply to the use of mineral or inorganic coloring matters. Manufacturers who use organic coloring matters of natural origin such as vegetable colors, should assure themselves that such substances are harmless in themselves and free from harmful impurities.

WHEN A CERTIFIED DYE BECOMES UNCERTIFIED

When a container of a certified dye is opened, the guaranty of its purity can no longer apply, inasmuch as no one other than the person or firm breaking the package can further assume responsibility for its purity and identity. Certified dyes that have been repacked, either without mixing or with the admixture of other certified dyes or suitable diluents or both, therefore can not properly be marketed as certified dyes or mixtures, unless they are recertified in the proper manner (p. 7). Dealers, mixers, and repackers of dyes should be particularly careful to observe this fact. The use of the word "certified" or the use of batch numbers, lot numbers, and the like on repacked dyes or color mixtures that have not been recertified creates a misleading impression, constituting a violation of the Federal food and drugs act if the products are brought within its jurisdiction.

This provision applies only to the resale of dyes and mixtures. It does not prevent the use of such expressions as "colored with a certified dye" in advertising or labeling food products artificially colored with certified dyes or mixtures.

THE PERMITTED DYES

The following coal-tar dyes are accepted for certification as described on pages 3 to 6. (The first number in each line is that of the dye as listed in the Colour Index of 1924, published by the Society of Dyers and Colourists of England. Where no number is given the dye is one which has been especially developed for use as a food color and has not yet been included in the Colour Index.

Red shades:
- 80 Ponceau 3R.
- 184 Amaranth.
- 773 Erythrosine.
- Ponceau SX.

Orange shade:
- 150 Orange I.

Yellow shades:
- 10 Naphthol yellow S.
- 640 Tartrazine.
- 22 Yellow A B.
- 61 Yellow OB.
- Sunset yellow F C F.

Green shades:
- 666 Guinea green B.
- 670 Light green S F yellowish.
- Fast green F C F.

Blue shades:
- 1180 Indigotine.
- Brilliant blue F C F.

Yellow A B and Yellow O B are known as oil-soluble dyes, because they are soluble in edible oils but insoluble in water. The other 13 dyes are soluble in water but insoluble in oils.

The original list of seven permitted dyes was selected after a critical study of the reports of pharmacological tests on the more important dyestuffs.[1] The

[1] Hesse. Coal-tar colors used in food products. U. S. Dept. Agr., Chem. Bul. 147 (1912).

other eight dyes were added to the list after appropriate pharmacological and toxicological tests had proved them to be harmless.

DEFINITION OF TERMS

When used in these regulations,

Manufacturer means the person or firm responsible for the identity and purity of the product, or the accredited selling agent in the United States of such person or firm which is not resident within the jurisdiction of this Government. Such accredited agent must assume for his foreign principal all responsibilities which devolve upon the manufacturer resident within the United States.

Batch means that quantity of the dye which has received as a unit such treatment in the same manner and at the same time and place as shall render the product uniform in composition throughout its entire mass. The maximum size of a batch is limited only by the capacity of the equipment used to produce uniformity of composition.

Batch number is the number assigned by the manufacturer to the batch with his request for certification. It provides a convenient way of designating the various batches while they are undergoing examination in the Food and Drug Administration. The batch number must appear on all affidavits and agreements submitted for that batch and on the label of the sample submitted for examination.

Lot number is the number assigned to the batch by the Food and Drug Administration upon certification and shall appear upon the labels of all packages of that batch. The use of original lot numbers in the resale of certified colors under distributors' labels is permitted, provided the original package is unbroken and the words "packed for" or "distributed by" precede any name on the label other than that of the manufacturer.

STATEMENT OF DYE CONTENT ON PACKAGES OF PRIMARY DYES AND REPACKS

The manufacturer shall state plainly and conspicuously on the label of each package of a primary dye or a repack the percentage of pure coal-tar color present in the product as determined by the Food and Drug Administration, provided, however, that in the case of a dye of a pure color content, as determined by the Food and Drug Administration, equaling or exceeding the percentage specified in Table 1, he may, if he desires, declare on the label that the product contains not less than the percentage of pure coal-tar color specified for that dye in Table 1. No tolerance below the stated percentage will be allowed when the declaration is in terms of such minimum percentage.

TABLE 1.—*Tolerances for minimum percentage declarations*

Coal-tar dye	Tolerance	Coal-tar dye	Tolerance
	Per cent		*Per cent*
Ponceau 3 R	85	Tartrazine	86
Ponceau S X	85	Guinea green B	82
Amaranth	86	Light green S F Y	82
Erythrosine	85	Indigotine	86
Sunset yellow	85	Brilliant blue F C F	82
Orange I	88	Yellow A B	99
Naphthol yellow S	88	Yellow O B	99
Fast green F C F	82		

The right is reserved to change the limits given in Table 1 after due notice to the trade, whenever it seems desirable to do so.

CERTIFICATION REQUESTED

When a manufacturer has prepared his first batch of a permitted dye for the purpose of requesting certification, a representative sample of the batch should be analyzed by the methods prescribed by the Food and Drug Administration. If the analysis shows that the dye complies with the specifications of purity for that particular dye, he should execute a manufacturer's affidavit and agreement and have the examining chemist execute a foundation affidavit. The nature of

the affidavits and agreement required is indicated in the following approved forms: [2]

MANUFACTURER'S AFFIDAVIT

_____,
_____, *ss:*
Before me, a _____ personally appeared
(Title of officer administering oath)
the undersigned, in the county and State aforesaid, who, being first duly sworn, deposes and says: I, _____
(Name)
am _____
(State official title, if officer of corporation; if member of partnership, so state; if sole owner, so state)
of _____
(Name of corporation or partnership or name under which sole owner conducts business)
of _____; the material known as _____
(Address) (Name of dye)
hereto attached was manufactured by _____;
(Me or name of corporation or partnership)
the material corresponds to the coloring matter numbered _____ in Colour Index (1924), published by the Society of Dyers and Colourists of England; the accompanying affidavit, signed by _____ contains the report of an analysis of a fair, average
(Name of examining chemist)
sample drawn from batch number _____; the total weight of said batch is _____ pounds and the material hereto attached is a fair, average sample of said batch.

_____
(Signature)

Subscribed and sworn to before me, at _____, this _____ day of _____, 19____.
[SEAL]

_____
(Signature of officer administering oath)

_____
(Title of officer administering oath)

MANUFACTURER'S AGREEMENT [3]

If the batch mentioned in the foregoing affidavit is certified by the Food and Drug Administration, the undersigned agrees to place plainly and conspicuously on the label, which shall in every instance be attached to the package put up by _____ and containing any of the material
(Me or name of corporation or partnership.)
from said batch, the lot number assigned by the Food and Drug Administration and the following statement: [4]

This certified dye contained when packed
_____ per cent pure coal-tar dye.
OR
This certified dye contained when packed
not less than _____ per cent pure coal-tar dye.

The undersigned further agrees to keep available to representatives of the Food and Drug Administration at all reasonable hours for two years from date of certification complete records of the disposition of said batch and each and every part of it, including dates of and number of pounds in each delivery or shipment, or other disposition, and names and addresses of the persons or firms receiving the dye from
_____
(Me or name of corporation or partnership.)

_____
(Signature.)

_____,
_____, *ss:*
I hereby certify that on this _____ day of _____, 19__, before me,
a _____, _____,
(Title of officer) (Name of person signing agreement)
_____, of
(Sole owner, partner, or official title of officer or corporation)
_____
(Name of corporation or partnership or name under which sole owner conducts business)
who is personally known to me and who is known by me to be _____
_____, of
(Sole owner, partner, or official title of officer or corporation)
_____
(Name of corporation or partnership or name under which sole owner conducts business.)
personally appeared and did acknowledge that he signed the above agreement.

[SEAL.]

_____
(Signature of officer taking acknowledgment)

_____
(Title of officer taking acknowledgment)

---

[2] These forms must be made up by the certifiers and will not be furnished by the Food and Drug Administration.

[3] If more convenient to the person or firm requesting certification, the acknowledgment by officer may be replaced by the signature of a responsible person as witness.

[4] The form of labeling used and the percentage of dye declared shall agree with the requirements of "Statement of dye content on packages," as given on page 3.

FOUNDATION AFFIDAVIT

---,
---, *ss:*
Before me, a ---, personally appeared the
(Title of officer administering oath)
undersigned, in the county and State aforesaid, who, being first duly sworn, deposes and says: I, ---, residing at ---
(Name) (Street address)
in the city of ---, county of ---
State of ---, have personally examined and tested for ---, of the
(Full name of firm covered by manufacturer's affidavit)
city of ---, county of ---, State of ---
the sample described in the attached manufacturer's affidavit; the sample corresponds to the coloring matter numbered --- in Colour Index (1924), published by the Society of Dyers and Colourists of England; said sample consists of --- only;
(Name of color)
it is free from harmful constituents; it contains no contamination due to imperfect or incomplete manufacture; and the following is a complete and accurate report of my chemical analysis and my interpretation of results: (Here insert a complete statement of all tests applied to determine the identity of the dye, the absence of harmful mineral, metallic, or organic constituents and the absence of contamination due to improper or incomplete manufacture. There should be set forth the quantity or volume of each material and reagent employed, its strength or concentration, temperature, duration of treatment, limits of delicacy of tests employed, and all other information necessary to enable other chemists to repeat accurately all work herein reported. For each test performed the conclusions drawn and the reason for these conclusions should be stated. This should be followed by a brief summary of the results obtained, preferably in a table of two columns of figures, one showing the percentages of the substances actually found and the other the ratio of each of these percentages to the percentage of dye. The methods of analysis used should be those described in Department of Agriculture Bulletin 1390, with such additions or revisions as may be made rom time to time, or those known to and approved by the Food and Drug Administration.)

(Signature.)
Subscribed and sworn to before me, at ---, this --- day of ---, 19--.

[Seal.] ---
(Signature of officer administering oath.)

(Title of officer administering oath.)

These affidavits and agreement, attached to a 1-pound representative sample of the batch in the case of water-soluble dyes or a half-pound sample in the case of oil-soluble dyes, are sent to the Food and Drug Administration. The samples submitted should be packed in suitable containers and labeled conspicuously with the name and address of the manufacturer, the name of the dye, the batch number, and the total weight in pounds of the batch. For convenience, most manufacturers label their batches of each permitted dye in a consecutive series. The label should be securely attached to the container.

CERTIFICATION GRANTED

Upon receipt of the sample and properly executed affidavits and agreement by the Food and Drug Administration, the sample is examined chemically if the foundation affidavit indicates that the dye is of proper identity and purity. If the results obtained substantiate the claimed identity of the dye and its compliance with the standards of purity, a certificate assigning a lot number to the batch and reporting the dye content as determined by the administration is issued by the administration to the manufacturer. If the administration's examination shows that the product does not conform to the requirements for certification, the batch is rejected for use in foods. The chemical examination and the certification or rejection of the batch usually take approximately two weeks.

LOT NUMBER

The lot number assigned on certification applies only to that particular batch of dye and to no other batch of the same or another dye. It is to be used by the manufacturer on each container in which the batch is packed for commerce. It is the manufacturer's guaranty that the dye has been certified and as such can apply only to those containers in which it was originally packed by him.

CERTIFICATION OF SUBSEQUENT BATCHES

The certification of subsequent batches of the same dye is accomplished in exactly the same way as the certification of the first batch, except that a supplemental affidavit is submitted instead of a foundation affidavit and a smaller

sample is required. The facts necessary in the supplemental affidavit are indicated in the following approved form:[2]

SUPPLEMENTAL AFFIDAVIT

---, *ss:*
Before me, a ---, personally appeared the
(Title of officer administering oath)
undersigned, in the county and State aforesaid, who, being first duly sworn, deposes and says: I,
---, residing at ---,
(Name) (Street address)
in the city of ---, county of ---
State of ---, have personally examined and tested for---
---, of the city of
(Full name of firm covered by manufacturer's affidavit)
---, county of ,---, State
of ---, the sample described in the attached manufacturer's affidavit; the sample corresponds to the coloring matter numbered --- in Colour Index (1924), published by the Society of Dyers and Colourists of England; said sample consists of ---
(Name of color)
only; it is free from harmful constitutents; it contains no contamination due to imperfect or incomplete manufacture; and the following is a complete and accurate report of my chemical analysis, conducted in strict accordance with the detailed scheme of examination fully set forth in the foundation affidavit covering ---, sworn to by ---
(Name of dye) (Me, or, if
---, on ---, 19--:
another chemist, give name) (Date)
(Here insert a brief summary of the results obtained, preferably in the form of a table of two columns of figures, one showing the percentages of the substances actually found and the other the ratio of each of these percentages to the percentage of dye.)

(Signature)

Subscribed and sworn to before me at ---, this ---
day of ---, 19--.
[SEAL.] ---,
(Signature of officer administering oath)

(Title of officer administering oath)

The manufacturer's affidavit and agreement are identical in form with those required for original certification.

Only a half-pound sample of the water-soluble dyes or a one-fourth pound sample of the oil-soluble dyes need be submitted with the manufacturer's affidavit and agreement and the supplemental affidavit. The general procedure in labeling and packing the sample and in issuing a certificate assigning a lot number or in rejecting the batch is the same as that for the certification of the first batch. The lot number assigned applies only to the particular batch for which it is issued and to no other batch of the same or another dye or mixture. The time necessary for certification or rejection of subsequent batches is usually shorter than that for original batches, ordinarily only about one week being required.

RECERTIFICATION OF REPACKED DYES

When a certified dye is repacked it should be recertified by submitting to the Food and Drug Administration a secondary affidavit and agreement, with a one-fourth pound sample, packed and labeled as required for original certification. The facts required in the secondary affidavit and agreement are indicated in the following approved forms:[2]

SECONDARY AFFIDAVIT (FOR REPACKS)

---,
---, *ss:*
Before me, a ---, personally appeared the
(Title of officer administering oath)
undersigned, in the county and State aforesaid, who, being first duly sworn, deposes and says: I, ---
---
(Name)
am---
(State official title if officer of corporation; if member of partnership, so state; if sole owner, so state)
of ---;
(Name and address of corporation or partnership or name under which sole owner conducts business)
the material known as --- hereto attached is a fair, average sample
(Name of dye)
of batch number ---; said batch was made by repacking --- pounds of
certified ---, lot number ---, obtained from
(Name of dye)

[2] These forms must be made up by the certifiers and will not be furnished by the Food and Drug Administration.

---; said
(Name and address of person or firm from whom obtained)
batch was not otherwise mixed or treated in any way or manner.

(Signature)

Subscribed and sworn to before me at ---, this --- day of ---, 19--.

(Signature of officer administering oath)

(Title of officer administering oath)

SECONDARY AGREEMENT (FOR REPACKS) [5]

If the batch mentioned in the foregoing affidavit is certified by the Food and Drug Administration,[5] the undersigned agrees to place plainly and conspicuously on the label, which shall in every instance be attached to the package put up by ---
(Me or name of corporation or partnership)
and containing any of the material from said batch, the lot number assigned by the Food and Drug Administration and the following statement: [6]

This certified dye containes when packed
--- per cent pure coal-tar dye.
OR
This certified dye contained when packed
not less than --- per cent of pure
coal-tar dye.

The undersigned further agrees to keep available to representatives of the Food and Drug Administration at all reasonable hours for two years from date of certification complete records of the disposition of said batch and each and every part of it, including dates of and number of pounds in each delivery or shipment, or other disposition, and names and addresses of the persons or firms receiving the dye from ---, except that no record will be kept of the names and addresses of persons or firms receiving containers of three ounces or less, but the total quantity of color distributed through such deliveries shall be recorded.
(Me or name of corporation or partnership)

(Signature)

---,
---, *ss:*
I hereby certify that on this --- day of ---, 19--, before me, a
---, ---,
(Title of officer) (Name of person signing agreement)
---,
(Sole owner, partner, or official title of officer of corporation)
of ---,
(Name of corporation or partnership or name under which sole owner conducts business)
who is personally known to me and who is known by me to be ---
---
(Sole owner, partner, or official title of officer of corporation)
of ---,
(Name of corporation or partnership or name under which the sole owner conducts business)
personally appeared and did acknowledge that he signed the above agreement.
[SEAL.]

(Signature of officer taking acknowledgment)

(Title of officer taking acknowledgment)

The general procedure in issuing a certificate assigning a lot number or in rejecting the batch is the same as that for the previous certification. The new lot number assigned applies to the particular repacked batch for which it is issued and to no other batch of the same or any other dye or mixture. Affidavit, agreement, and sample must be submitted for each batch repacked. Certification or rejection of batches of repacked dyes requires ordinarily about one week.

CERTIFICATION OF MIXTURES

Color mixtures should be certified before sale.

A mixture is a color which is made from two or more certified dyes without any other added substance, or a color made from one or more certified dyes mixed with a harmless diluent suitable for use in foods and not of itself a coloring matter.

Adequate precautions must be taken to make sure that the mixture is homogeneous throughout and that liquid mixtures are clear and free from sediment.

The formula of a mixture is the quantitative statement of component dyes and mixtures, and the qualitative statement of diluents, etc., entering into the composition of the mixture. It includes the percentage of dye content claimed in the agreement regarding labeling.

Change of formula is any change in a given mixture involving the percentage dye content claimed in the agreement regarding labeling, variation in the relation of the color components to one another, or change in the identity of the diluents.

---

[5] If more convenient to the person or firm requesting certification, the acknowledgment by officer may be replaced by the signature of a responsible person as witness.

[6] The form of labeling used and the percentage of dye declared shall agree with the requirements under "Statement of dye content of packages," as given on page 3.

Formulas for mixtures are held confidential by the Food and Drug Administration.

Certified mixtures are ordinarily sold under trade names. The name chosen should be simple and in no way ambiguous or misleading, and should not include the names of fruits or vegetables without any qualifying statement. No firm or person should use for mixtures of different formulas names or designations of such resemblance that the products to which they are applied may be confused with one another, but if a change in formula of a certified mixture having an established trade name becomes justified, the mixer or responsible officer of the mixing firm may submit an affidavit setting forth the facts on which the change is based and stating that all the materials made under the old formula will be used before any made under the new formula are placed on the market. If the facts in the affidavit justify an alteration in the formula, approval for the change will be given.

Certification of color mixtures is accomplished by submitting to the Food and Drug Administration a secondary affidavit and agreement, with a one-fourth pound representative sample of the mixture, packed and labeled as required for original certification, except that the label may bear the trade name in lieu of the names of the dyes present. The facts required in the secondary affidavit and the agreement are indicated in the following approved forms: [2]

SECONDARY AFFIDAVIT (FOR MIXTURES)

----------,
----------, *ss.*
Before me, a ----------, personally appeared
(Title of officer administering oath)
the undersigned in the county and State aforesaid, who, being first duly sworn, deposes and says: I, ------
----
(Name)
am ----------
(State official title if officer or corporation; if member of partnership, so state; if sole owner, so state)
of ----------;
(Name and address of corporation or partnership or name under which sole owner conducts business)
the material known as ---------- hereto attached is a fair, average
(Name of mixture)
sample of batch number ----------; said batch was made by mixing ---------- pounds of certified
----
(Name of dye or mixture)
lot number ----------, obtained from ----------
(Name and address of person or firm from whom obtained)
(repeat for each dye or mixture used) and ---------- pounds of ----------
(Name of diluent)
(repeat for each diluent used); said batch was made from these ingredients and none other; the total weight of said batch is -------- pounds; said batch was thoroughly mixed to insure uniformity.

(Signature)
Subscribed and sworn to before me, at ----------, this ----------
day of ----------, 19--
[SEAL.]

(Signature of officer administering oath)

(Title of officer administering oath)

SECONDARY AGREEMENT (FOR MIXTURES) [7]

If the batch mentioned in the foregoing affidavit is certified by the Food and Drug Administration, the undersigned agrees to place plainly and conspicously on the label, which shall in every instance be attached to the package put up by ---------- and containing any
(Me or name of corporation or partnership)
of the material from said batch, the lot number assigned by the Food and Drug Administraction, the designation under which the batch is certified, and the following statement:

This certified dye contained when packed
not less than -------- per cent pure coal-
tar dye.

The undersigned further agrees to keep available to representatives of the Food and Drug Administration at all reasonable hours for two years from date of certification complete records of the disposition of said batch and each and every part of it, including dates of and number of pounds in each delivery or shipment, or other disposition, and names and addresses of the persons or firms receiving the dye from ----------
----------, except that the names and addresses of persons or firms
(Me or name of corporation or partnership)
receiving quantities of three ounces or less shall not be recorded, but a record shall be made of the total quantity of color distributed through such deliveries.

(Signature)

---

[2] These forms must be made up by the certifiers and will not be furnished by the Food and Drug Administration.

[7] If more convenient to the person or firm requesting certification, the acknowledgment by officer may be replaced by the signature of a responsible person as witness.

---,
---, *ss:*
I hereby certify that on this ---- day of ----, 19--, before me, a ----
---, ---,
(Title of officer) (Name of person signing agreement)
---,
(Sole owner, partner, or official title of officer of corporation)
of ---,
(Name of corporation or partnership or name under which sole owner conducts business)
who is personally known to me and who is known by me to be ---
(Sole owner, partner, or official title of officer of corporation)
of ---,
(Name of corporation or partnership or name under which sole owner conducts business)
personally appeared and did acknowledge that he signed the above agreement.

[SEAL] ---
(Signature of officer taking acknowledgment)

(Title of officer taking acknowledgment)

The general procedure in issuing a certificate assigning a lot number or in rejecting the batch is the same as for the original certification of the dyes. The lot number assigned applies only to that particular batch of the mixture for which it is issued and to no other batch of the same or other mixture or straight dye. Affidavit, agreement, and sample must be submitted for each batch of mixture made.

Certification or rejection of batches of mixtures requires ordinarily about one week.

A certified mixture may be repacked and recertified, or it may be used as a constituent of another mixture for which certification is requested. Samples of repacked mixtures submitted with requests for recertification should be packed and labeled in accordance with the procedure outlined for the original certification of mixtures, and the procedure otherwise is identical with that of original certification, except that the form of secondary affidavit and agreement required for recertification of repacked dyes is used, substituting the words "certified mixture" for "certified dye."

GENERAL LABELING REQUIREMENTS

In addition to the labeling covered by the agreement submitted with samples for certification, the general provisions of the Federal food and drugs act regarding labels should be observed if the dye is distributed in interstate commerce. These require that the containers bear a plain and conspicuous statement of the quantity of the contents and prohibit the use of statements, designs, or devices that are false, misleading, or deceptive. If, owing to the absorption of moisture or other cause, the dye content falls below the labeled declaration before interstate shipment, the product is in violation of the law, even if the declaration is the one reported by the Food and Drug Administration at the time of certification.

ADMISSION OF ADDITIONAL DYES

To be considered suitable for inclusion in the list of permitted coal-tar food colors, a dye must not be protected in any way by unexpired patents covering either the dye itself or the only known methods of preparing it or any of its intermediates. Its complete process of manufacture must have been described in some recognized scientific publication. Names chosen for new dyes to be certified should not be false or misleading in any particular and no element in them should tend to advertise the product of any particular manufacturer.

Manufacturers wishing to have a dye added to the permitted list should prepare the dye in as pure a form as possible and submit to the Food and Drug Administration a manufacturer's affidavit and agreement, a foundation affidavit, and a detailed report by one or more reputable pharmacologists and toxicologists on the pharmacological and toxicological properties of the dye. When a knowledge of the process of manufacture is necessary to determine the identity of the dye, the submission in the manufacturer's affidavit of a complete description of certain steps or all steps in the manufacturing procedure may be required. To these reports should be attached a 5-pound sample of the dye taken from the same batch as that from which the sample used for analysis and pharmacological and toxicological investigations was obtained. If the data submitted indicate the suitability of the dye for food use, the Food and Drug Administration proceeds with chemical, pharmacological, and toxicological examinations of the sample.

If these investigations show that the dye is harmless and of suitable purity, it is added to the permitted list, provided need for a new dye can not be met by dyes already on the list, or other sufficient reason obtains. The time required for these investigations is necessarily long; in most cases about two years will probably be needed.

The contemplated addition of a dye to the permitted list will be published by the Food and Drug Administration at least two months before its admission. In the case of newly developed dyes, this announcement will not appear in advance of the description in a recognized scientific publication of the complete process of manufacture of the dye.

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